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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,941	12/29/2004	Masaya Tanaka	0020-5615PUS1	5052
2252	7590	03/13/2009	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			OSTRUP, CLINTON T	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			3771	
NOTIFICATION DATE		DELIVERY MODE		
03/13/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,941	<b>Applicant(s)</b> TANAKA, MASAYA
	<b>Examiner</b> CLINTON OSTRUP	<b>Art Unit</b> 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/6/09 & 2/6/09.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4 and 6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/96/08)  
 Paper No(s)/Mail Date 1/6/09
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. This Office Action is in response to the amendment filed January 6, 2009. As directed by the amendment, claims 1, 2 and 4 have been amended and claims 3, 5 and 7-12 have been cancelled. Thus, claims 1, 2, 4 and 6 are pending in this application.

#### ***Specification***

2. The disclosure is objected to because of the following informalities: the use of the trademark TETRA CO<sub>2</sub>™ has been noted in this application on page 23, 27, and 28. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Thus, the symbol “™” or the symbol “®” should follow the trademark name.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339) and further in view of Regnard et al.,**

(BMJ 1997; 315:1002-1005 (18 October) Clinical review ABC of palliative care:

Mouth care, skin care, and lymphoedema), herein referred to as Regnard et al.

Regarding claim 1, Nishino discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) for sealing a body surface from the outside air; the sealing enclosure member holds carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide into the inside space of the sealing enclosure member; and an absorption aid (water) that is provided in the inside space of the sealing enclosure member, contains a carbon dioxide-dissolving medium (water) for dissolving carbon dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide.

See: [0008-0015] and figure 1.

However, Nishino lacks the absorption aid containing at least one carbon dioxide-dissolving aid containing a carbon dioxide-dissolving medium which comprises calcium alginate hydrogel and at least one carbon dioxide-dissolving medium selected from the group consisting of (a) alcohols having a high vaporization temperature, (b) oils and fats, and (c) waxes.

Tanaka et al teaches a carbon dioxide external administration device with a carbon dioxide absorption aid that contains a carbon dioxide dissolving medium in the form of an emulsion or a cream and said emulsion or cream comprising at least an oil or fat, a surfactant and water. See: Tanaka et al., See: col. 2, lines 36 - col. 9, line 57. Tanaka also teaches forming aqueous viscous compositions in the form of gels and

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specifically utilizes alginates as a thickener. See: col. 7, lines 43-46, Tables 1-25 and claims 1, 3, and 9.

Regnard et al. teaches using calcium alginate hydrogels as dressings for the treatment of deep skin ulcers to encourage granulation. See: Skin Care, Dressing for ulcers.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the absorption aid (water) of Nishino, by using an aqueous viscous gel composition as taught by Tanaka with alcohols having high vaporization temperatures and oils and fats in order to provide an absorption aid that provides "improved skin comfort, usability, and the like of the composition by adding a perfume, color material, moisturizer, oily component..." See: Tanaka col. 9, lines 13-50 utilizing a calcium alginate hydrogel that is typically used in the treatment of skin ulcers, as taught by Regnard.

Regarding claim 4, Tanaka teaches incorporating carbon dioxide containing viscous compositions into a sheet for topically applying carbon dioxide gas to skin. See: col. 3, line 65 - col. 4, line 3; col. 12, lines 4-33; col. 43, lines 38 - col. 44, line 58.

Regarding claim 6, Nishino discloses a carbon dioxide external administration device with a sealing enclosure member (1 or 11) that is made from a flexible material having a shape holding ability (when inflated), an elastic and flexible material (it expands and contracts as it is inflated) formed into a shower cap or a boot.

5. **Claim 2 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on**

**the English Equivalent US 6,689,339) in view of Regnard et al., (BMJ 1997;315:1002-1005 (18 October) Clinical review ABC of palliative care: Mouth care, skin care, and lymphoedema), herein referred to as Regnard et al. and further in view of Westwood (WO 98/173340).**

The combined references disclose all the limitations of claim 2, except the carbon dioxide amount indicator being provided separately from the sealing enclosure member.

Westwood teaches a sealing enclosure member (10) with a valve (18) that would expand (open) when carbon dioxide is supplied into the sealing enclosure member (at least at a given pressure) and contracts (closes) when the amount of carbon dioxide decreases (when the pressure falls below the given pressure). See: figures 1-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a valve, as taught by Westwood, to the boot device disclosed by the combined references, in order to determine when the optimal amount of carbon dioxide pressure is being applied to the user.

#### ***Response to Arguments***

6. Applicant's arguments with respect to claim 1, 2, 4 and 6 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771